CERTIFICATE OF NEED – RELEVANT EXCERPTS FROM PUBLIC ACT 368 OF 1978 (AS AMENDED)

Michigan Department of Health & Human Services CERTIFICATE OF NEED

South Grand Building 333 S. Grand Avenue, 4th Floor Lansing, Michigan 48933 (517) 241-3344 - Fax (517) 241-2962

AUTHORITY: PA 368 of 1978, as amended

COMPLETION: Is **Voluntary**, but is required to obtain a

Certificate of Need. If NOT completed, a Certificate of Need will NOT be issued.

The Department of Health & Human Services is an equal opportunity employer, services and programs provider.

Section 22223 of P.A. 368 of 1978, as amended, states:

An applicant for a certificate of need shall include, as part of the application, a statement addressing each of the review criteria listed in section 22225. This section does not apply to an application for a Certificate of Need made under section 22210.

An application cannot be deemed received without responses to each section in this form.

Sec. 22225. (1) In order to be approved under this part, an applicant for a Certificate of Need shall demonstrate to the satisfaction of the department that the proposed project will meet an unmet need in the area proposed to be served. An applicant shall demonstrate the need for a proposed project by credible documentation of compliance with the applicable certificate of need review standards. If no Certificate of Need review standards are applicable to the proposed project or to a portion of a proposed project that is otherwise governed by this part, the applicant shall demonstrate to the satisfaction of the Department that an unmet need for the proposed project or portion of the proposed project exists by credible documentation that the proposed project will be geographically accessible and efficiently and appropriately utilized, in light of the type of project and the existing health care system. Whether or not there are applicable Certificate of Need review standards, in determining compliance with this subsection, the Department shall consider approved projects that are not yet operational, proposed projects under appeal from a final decision of the Department, or proposed projects that are pending final Department decision.

[Note: Response should state that the applicant has complied or not complied with the applicable standards. For example, "The applicant has demonstrated compliance with the CON Review Standards for Open Heart Surgery Services and Cardiac Catheterization Services assigned to this proposed project." For projects categorized as a capital expenditure or part of the project is categorized as such, the applicant must provide a detailed summary of the need for the proposed project as no standards currently exist for these types of project.]

CON-200 (04-15) Page 1 of 5

(2)	If, and only if, the requirements of subsection (1) are met, in order for an application to be approved under this part, an applicant shall also demonstrate to the reasonable satisfaction of the Department all of the following:
(a)	With respect to the method proposed to meet the unmet need identified under subsection (1), that the applicant has considered alternatives to the proposed project and that, in light of the alternatives available for consideration, the chosen alternative is the most efficient and effective method of meeting that unmet need.
	ŭ

- (b) With respect to the financial aspects of the proposed project, that each of the following is met:
- (i) The capital costs of the proposed project will result in the least costly total annual operating costs.
- (ii) Funds are available to meet the capital and operating needs of the proposed project.
- iii) The proposed project utilizes the least costly method of financing, in light of available alternatives.
- iv) In the case of a construction project, the applicant stipulates that the applicant will competitively bid capital expenditures among qualified contractors or alternatively, the applicant is proposing an alternative to competitive bidding that will achieve substantially the same results as competitive bidding.

[Note: Applicants are required to respond to each subsection of this part of Code in form CON-1100.]

CON-200 (04-15) Page 2 of 5

- (c) The proposed project will be delivered in compliance with applicable operating standards and quality assurance standards approved under section 22215(1)(b), including 1 or more of the following:
- (i) Mechanisms for assuring appropriate utilization of the project.
- (ii) Methods for evaluating the effectiveness of the project.
- (iii) Means of assuring delivery of the project by qualified personnel and in compliance with applicable safety and operating standards.
- (iv) Evidence of the current and historical compliance with federal and state licensing and certification requirements in this state by the applicant or the applicant's owner, or both, to the degree determined appropriate by the commission in light of the subject of the review standard.
- (v) Other criteria approved by the commission as appropriate to evaluate the quality of the project.

[Note: Please respond to this subsection with the following statement: "By submission of this application, I, as the authorized agent, certify that the applicant will abide by the agreements and assurances cited in the project delivery requirements section of the applicable CON Review Standards for this application. For capital expenditure projects, the applicant should respond with the following statement: "Pursuant to PA 368 of 1978, this statutory requirement is not applicable to this application since the Certificate of Need (CON) Commission has not yet approved operating or quality assurance standards under Section 22215(1)(b) applicable to this project."]

- (d) The health services proposed in the project will be delivered in a health facility that meets the criteria, if any, established by the commission for determining health facility viability, pursuant to this subdivision. The criteria shall be proposed by the Department and the office, and approved or disapproved by the commission. At a minimum, the criteria shall specify, to the extent applicable to the applicant, that an applicant shall be considered viable by demonstrating at least 1 of the following:
- (i) A minimum percentage occupancy of licensed beds.
- (ii) A minimum percentage of combined uncompensated discharges and discharges under title XIX of the social security act in the health facility's planning area.
- (iii) A minimum percentage of the total discharges in the health facility's planning area.
- (iv) Evidence that the health facility is the only provider in the health facility's planning area of a service that is considered essential by the commission.
- (v) An operating margin in an amount determined by the commission.
- (vi) Other criteria approved by the commission as appropriate for statewide application to determine health facility viability.

[Note: The CON Commission has not yet established criteria to determine health facility viability pursuant to Section 22215(1)(d). Therefore, no response is required.]

(e) In the case of a nonprofit health facility, the health facility is in fact governed by a body composed of a majority consumer membership broadly representative of the population served.

[Note: Response should include total number of board members, total number of consumers, total number of providers and total number of members by gender.]

CON-200 (04-15) Page 3 of 5

[Only if (e) is not met, respond to section below.] In the case of a health facility sponsored by a religious organization, or if the nature of the nonprofit health facility is such that the legal rights of its owners or sponsors might be impaired by a requirement as to the composition of its governing body, an advisory board with majority consumer membership broadly representative of the population served may be construed by the Department to be equivalent to the governing board described in this subdivision, if the advisory board meets all of the following requirements: (i) The role assigned to the advisory board is meaningful, as determined by the Department. (ii) The functions of the advisory board are clearly prescribed. (iii) The advisory board is given an opportunity to influence policy formulation by the legally recognized governing body, as determined by the Department.	
Health Maintenance Organization; Considerations and Criteria	
 Sec. 22227(3) In making determinations and conducting reviews for Certificates of Need for health maintenance organizations, the Department shall consider the special needs and circumstances of health maintenance organizations, and shall apply all of the following criteria: (a) The availability of the proposed service from a provider of health care other than the health maintenance organization on a long-term basis, at reasonable terms, and in a cost-effective manner consistent with the health maintenance organization's basic method of operation. (b) The long-term needs of the health maintenance organization, and its current and expected future membership. (c) Other criteria approved by the commission as appropriate for statewide application to determine health facility viability. (d) The long-term impact of the proposed service on health care costs in the health maintenance organization's service area. 	
Participation in Medicaid Program as Distinct Criterion	
Sec. 22230. In evaluating applications for a health facility as defined under section 22205(1)(c) in a comparative review, the department shall include participation in title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396r-6 and 1396r-8 to 1396v, as a distinct criterion, weighted as very important, and determine the degree to which an application meets this criterion based on the extent of participation in the medicaid program.	
[Note: Applicable to Nursing Homes/Hospital Long Term Care Units only.]	

CON-200 (04-15) Page 4 of 5

ATTACHMENT

CON Commission Actions with Regard to Part 222

Pursuant to Part 222 of Act 368 of the Public Acts of 1978, as amended, the CON Commission may periodically modify Standards and other requirements as set forth in Part 222.

CON Commission Actions With Regard to Section 22203(4)

Section 22203(4) defines a CON review standard to mean a standard approved by the Commission under Section 22215. Please see form CON-145 for a listing of the effective dates of the most current CON Review Standards. It is an applicant's responsibility to determine the current CON review standards applicable to a proposed project.

CON Commission Actions with Regard to Section 22203(10) and 22209(1)

Under Section 22203(10), a covered clinical service, except as otherwise modified by the Commission under Section 22215, means one or more of the following services listed below. Pursuant to Part 222, the CON Commission may periodically modify the list of covered clinical services. It is an applicant's responsibility to determine if a proposed project involves a service that currently is subject to review.

- Air Ambulance Services
- Bone Marrow Transplantation Services
- Cardiac Catheterization Services
- Computed Tomography (CT) Scanner Services
- Heart/Lung and Liver transplantation Services
- Magnetic Resonance (MRI) Services
- Megavoltage Radiation Therapy Services/Units
- Neonatal Intensive Care Services/Beds (NICU)
- Open Heart Surgery Services
- Positron Emission Tomography (PET) Scanner Services
- Surgical Services (includes hospitals, freestanding surgical centers, ambulatory surgery centers)
- Urinary Extracorporeal Shock Wave Lithotripsy Services

CON Commission Actions with Regard to Section 22203(5) and 22209(1)

Under sections 22203(5) and 22209(1), a covered beds/facility, except as otherwise modified by the Commission under Section 22215, means one or more of the beds/facilities listed below. It is an applicant's responsibility to determine if a proposed project involves a covered beds/facility that currently is subject to review.

- Hospital Beds
- Nursing Home and Hospital Long-Term-Care Unit Beds
- Psychiatric Beds and Services

CON-200 (04-15) Page 5 of 5